

JUN 07 2007

Serial No. 10/624,389  
Response dated June 7, 2007  
Reply to Office Action dated March 7, 2007  
Attorney Docket No. PF01022US

**REMARKS**

The applicants have studied the Office Action dated March 7, 2007, and have made amendments to the claims. By virtue of this amendment, claims 7-9 and 75-94 have been canceled without prejudice or disclaimer; thus, claims 1-6 and 10-34 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-34 and 75-94 were rejected under 35 U.S.C. § 102(e) as being anticipated by Campbell et al. Claims 1-34 and 75-94 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Estes et al. With respect to claims 7-9 and 75-94, these claims have been canceled without prejudice or disclaimer; thus, these rejections are now moot. With respect to pending claims 1-6 and 10-34, these rejections are respectfully traversed.

Embodiments of the present invention are directed to an infusion system including a characteristic determining device that determines a concentration of an analyte in a user, and an infusion device that infuses a fluid into the user. The characteristic determining device includes a determining device communication system that transmits a communication including data indicative of the determined concentration of the analyte in the user, and the infusion device includes an infusion device communication system that receives the communication from the determining device communication system. The infusion device also includes an infusion device processor that processes the data indicative of the determined concentration of the analyte in the user, and a bolus estimator used in conjunction with the infusion device processor that calculates an estimated amount of fluid to be infused into the user based upon the received data indicative of the determined concentration of the analyte in the user and a target concentration of the analyte in the user. The infusion device processor is further able to determine an amount of time that has elapsed since the concentration of the analyte in the user was determined, and causes the bolus estimator not to calculate the estimated amount of fluid to be infused based upon the determined

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concentration of the analyte if the elapsed amount of time exceeds a predetermined amount of time. In some instances, there may be a delay in the characteristic determining device between when it determines the concentration of the analyte in the user, and when it transmits the communication including the data indicative of the determined concentration of the analyte in the user to the infusion device. There may also be a delay in the infusion device between when the concentration of the analyte in the user is determined and received, and when the bolus estimator calculates the estimated amount of fluid to be infused into the user based upon the received data indicative of the determined concentration of the analyte in the user. However, in such instances, embodiments of the present invention can help to ensure that the estimated amount of fluid to be infused into the user is calculated only if the determined concentration of the analyte in the user upon which the calculation is based is sufficiently current, which is important because the concentration of the analyte can vary significantly over time for many users.

Both the Campbell et al. and Estes et al. references disclose an external infusion device that includes a bolus estimator for calculating an estimated amount of fluid to be infused into the user based on factors such as the amount of carbohydrates to be consumed by the user as well as the user's current and desired blood glucose levels. Additionally, the infusion device can receive the user's current blood glucose level from a blood glucose measurement device or glucose monitor, and the bolus estimator can calculate the estimated amount of fluid to be infused into the user based on the received current blood glucose level of the user. However, neither the Campbell et al. nor the Estes et al. reference discloses that the infusion device is further able to determine an amount of time that has elapsed since the user's blood glucose level was determined, and cause the bolus estimator not to calculate the estimated amount of fluid to be infused based upon the determined blood glucose level of the user if the elapsed amount of time exceeds a predetermined amount of time. In other words, the infusion device of the Campbell et al. and Estes et al. references fails to check whether the user's current blood glucose level received from the blood glucose measurement device or glucose monitor is sufficiently current prior to utilizing the received current blood glucose level as input to the bolus estimator.

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By contrast, independent claim 1 of the present application has been amended to recite that the infusion device processor determines an amount of time that has elapsed since the concentration of the analyte in the user was determined, and causes the bolus estimator not to calculate the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the elapsed amount of time exceeds a predetermined amount of time. As a result, claimed embodiments of the present invention ensure that the amount of fluid to be infused into the user is calculated only if the determined concentration of the analyte in the user upon which the calculation is based is sufficiently current.

For these reasons, the applicants respectfully submit that the Campbell et al. and Estes et al. references fail to disclose, teach, or suggest an infusion system which includes a characteristic determining device for determining the concentration of an analyte in a user and an infusion device including a bolus estimator for calculating an estimated amount of fluid to be infused into the user based upon data indicative of the determined concentration of the analyte in the user received from the characteristic determining device, and in which the infusion device processor determines an amount of time that has elapsed since the concentration of the analyte in the user was determined, and causes the bolus estimator not to calculate the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the elapsed amount of time exceeds a predetermined amount of time, as in the claimed embodiments. Therefore, independent claim 1, and claims 2-6 and 10-34 depending therefrom, are patentable over the Campbell et al. and Estes et al. references. Accordingly, withdrawal of the rejections of the claims under 35 U.S.C. § 102(e) is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all of the pending claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.


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If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney at (818) 576-5291.

Respectfully submitted,

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By:   
Vivian S. Shin  
Reg. No. 43,919

MEDTRONIC MINIMED, INC.  
18000 Devonshire Street  
Northridge, CA 91325  
Telephone: (818) 576-5291  
Facsimile: (818) 576-6202